Early Bone Grafting with the Functional Cleft Lip Repair

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ABSTRACT

The treatment of complete clefts of the lip and palate is controversial; many protocols and surgical techniques are utilized. In addition, long-term outcome assessments of these many clinical approaches are generally not available. In contrast, the protocol presented here, which includes presurgical orthopedics in the form of a passive palatal plate, functional cleft lip repair, and primary (early) autogenous bone grafting, has been followed without modification since its inception in 1965. Numerous long-term studies that include examination of graft survival, effect on facial growth, integrity of the dentition adjacent to the cleft, and subsequent need for orthognathic surgery are discussed. This protocol results in a successful outcome for the child with a complete cleft of the lip and palate. The appliance fabrication, cleft lip repair, and bone graft placement are uncomplicated and technically easy to learn. Most important, the results (i.e., maxillary growth, esthetic and functional results of lip repair, and occlusion) are impressive in spite of a protocol that is straightforward and can be followed incorporating any type of lip repair with muscle realignment and any palate closure that results in an early complete closure.

KEYWORDS: Functional lip repair, palatal prosthesis, early alveolar bone graft

The treatment of complete clefts of the lip and palate continues to be controversial, with many protocols utilizing different surgical techniques and variations in timing and numbers of interventions. Esthetics, function, and long-term effect on facial growth can present conflicting goals. In 1973, Koberg[1] did an extensive review of the literature and concluded that the multitude and complexity of the type of cleft, timing of surgery, and surgical techniques presented many unanswered questions. In addition, he stated that there was a lack of long-term outcome assessments, and generally his conclusions are still true today. Currently, some form of presurgical orthopedics combined with early periosteoplasty and/or secondary bone grafting along with different techniques for the timing and type of lip and palate surgery represent the most popular approaches for the child born with complete cleft lip and palate. Long-term outcome assessments of these various clinical approaches are, however, still not readily available.

In contrast, our approach, which includes presurgical orthopedics, functional cleft lip repair, and primary (early) alveolar bone grafting, has been followed without modification since its inception in 1965 (at Children's Memorial Hospital, Chicago). This has allowed numerous long-term studies that include examination of graft survival, effect on facial growth, volume of alveolar bone,

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Table 1 Protocol for Early Alveolar Bone Grafting

Age	Intervention
First 2 weeks of life	Maxillary impression for construction and placement of passive self-retaining appliance prior to lip closure
6–10 weeks of age	Functional cleft lip repair
10 weeks to 5 months	Appliance in place to control molding of segments by maintaining arch width posteriorly and allowing anterior segment approximation without collapse
5–8 months	Abutted segments stabilized with onlay, subperiosteal alveolar bone graft
8–12 months	Appliance in place in the mouth at least 6 weeks after graft or until palate repair
8–12 months	Complete palate repair

integrity of the dentition, and need for orthognathic surgery. The protocol is unique and follows a consistent sequence of procedures and interventions. The presurgical orthopedics, techniques of the functional cleft lip repair, and primary alveolar bone graft placement as separate and distinct surgeries, as well as the results of long-term studies, are presented here.

PROTOCOL FOR EARLY BONE GRAFTING WITH THE FUNCTIONAL CLEFT LIP REPAIR

The protocol for early primary bone grafting with the functional cleft lip repair in children with complete clefts of the lip and palate follows distinct and sequential steps (Table 1).

Passive, Self-Retaining Appliance Placed Initially

Presurgical orthopedics is accomplished with a passive, self-retaining appliance. During the first few weeks of life, in an outpatient setting, a dental impression is made of the segments of the maxillary arch. An appliance is constructed, placed, and worn continuously except for weekly removal for cleaning[2] (Fig. 1). It is essential to understand that the uniqueness of this appliance is that retention is derived from the undercut areas of the cleft, not primarily from adaptation over the alveolus, and this generally allows one appliance to be used until palate closure. This also maintains posterior width of the maxilla, prevents collapse of the segments, and allows molding and growth of the alveolar segments to abut before the lip repair is performed. A secondary benefit of this appliance is that it facilitates feeding by providing a "false palate" for compression of the nipple on the bottle during sucking (Fig. 2).

FUNCTIONAL CLEFT LIP REPAIR PERFORMED

The functional cleft lip repair with muscle realignment was described by Kernahan in 1978.[3] Although many repairs now incorporate some type of muscle repair, this repair is based on a thorough understanding of the

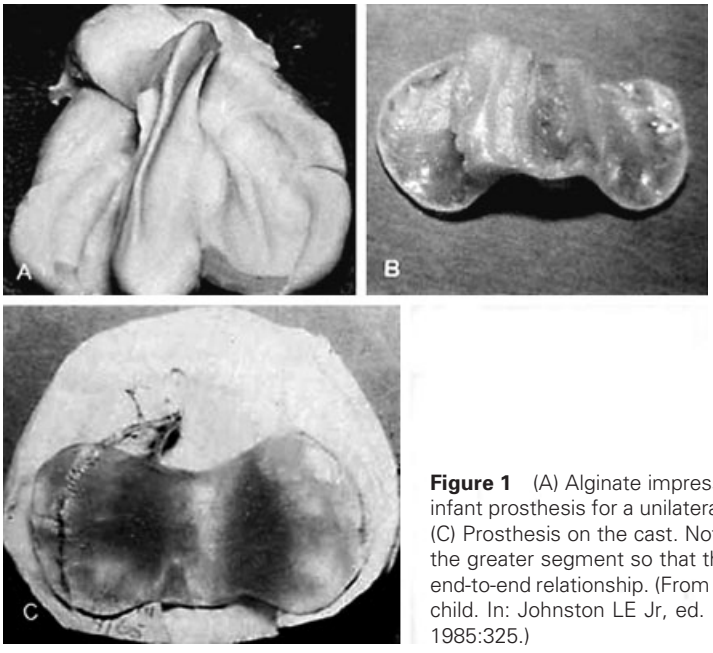

Figure 1 (A) Alginate impression of a complete unilateral cleft. (B) Superior view of an infant prosthesis for a unilateral cleft. Soft and hard acrylics have been bonded together. (C) Prosthesis on the cast. Note the position of the anterior margin of the prosthesis on the greater segment so that the action of the repaired lip will mold the segments to an end-to-end relationship. (From Rosenstein SW. Early habilitation of the cleft lip and palate child. In: Johnston LE Jr, ed. New Vistas in Orthodontics. Philadelphia: Lea & Febiger; 1985:325.)

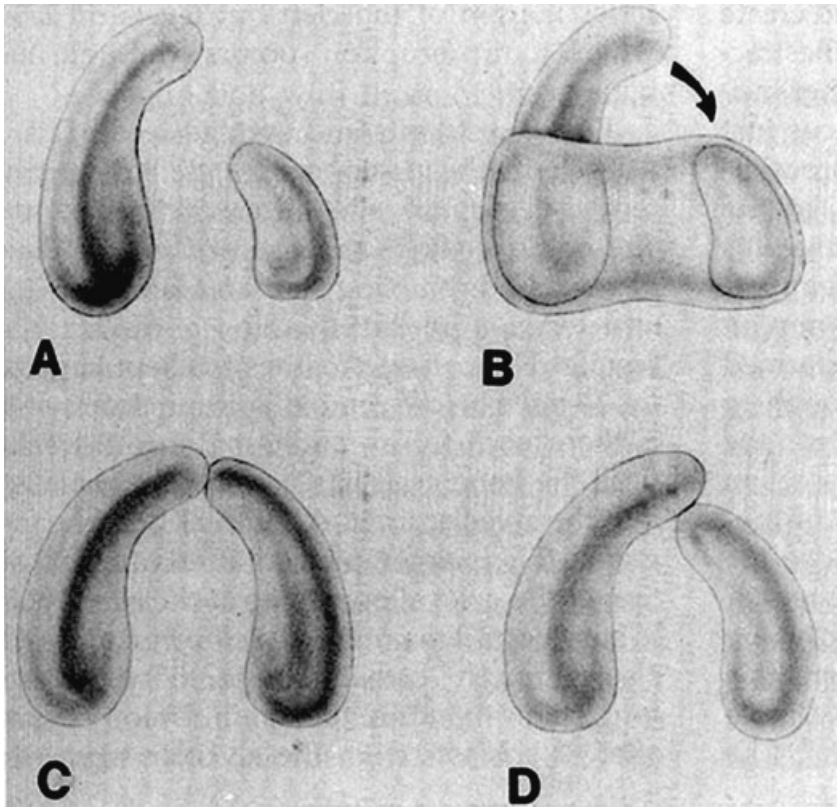

Figure 2 (A) Alveolar arch alignment before cleft is repaired. (B) Palatal appliance prevents alveolar arch collapse after lip repair. Arrow indicates direction of growth and molding of alveolus achieved with cleft lip closure. (C) Position of alveolar segments at a time of bone graft. There is a butt joint and good arch alignment. (D) Alveolar arch collapse when presurgical orthopedics not utilized. (From Kernahan DA, Rosenstein SW, eds. Cleft Lip and Palate; a System of Management. Baltimore: Williams & Wilkins; 1990:182.)

anatomy of the orbicularis oris muscle[3–5] and is unique because it treats the mucosa, muscle, and skin of the lip in separate layers and approaches the repair of the lip using a basic technique of tissue lengthening, namely the Z-plasty.

The essence of the lip repair is as follows (Fig. 3). Key landmarks of the lip and nose are marked on the lip. The edges of the cleft are pared and a thin strip of skin and mucosa removed. Mucosal flaps are turned back and the muscle on the lateral side of the cleft is dissected free from its insertions into the dermis and inferior lip border. The mucosa is similarly freed up from the muscle. The muscle is cut away from its alar attachment; this dissection and back cut eliminate the orbicularis bulge under the skin and lengthen the lateral side of the cleft. On the medial side of the cleft, a pocket is created near the nasal spine and at the inferior lip border. The dermal edge is then freed up from its fibrous attachment and the mucosa is dissected free as on the lateral side of the cleft. The mucosal flaps are sutured to create the first layer of closure; this in turn creates a buccal sulcus and eliminates a perialveolar fistula. Several sutures are then placed to close the skin side of the nasal floor. The superior border of the orbicularis oris muscle on the lateral side of the cleft is then advanced and sutured to the region of the nasal spine; the muscle is then split horizontally, dividing it into a lower one third and superior two thirds. The lower one third is advanced and sutured into the pocket at the medial lip border to create a philtral tubercle. The rest of the muscle is sutured to the fibrous material and a few muscle fibers on the medial side of the cleft. At this point in the procedure, the gap between the medial and lateral skin edges has been minimized, thus preventing tension at the suture line. A suture is tied at the white roll of the medial and lateral sides of the lip and held on tension. Z-plasty flaps are created at the upper portion of the lip; the medial cut does not cross the midline. These flaps lengthen the lip and help to adjust the nostril floor. Often, additional length is needed and a second smaller Z-plasty is created just above the white roll of the lip.

The lip repair is performed with the palatal appliance in place. After 10 days the appliance can be removed for cleaning, but it is used for at least 8 weeks after the placement of the alveolar bone graft. The lip repair with orbicularis oris realignment and a recreation of the oral sphincter allows growth and molding of the alveolar segments in a controlled environment and without palatal collapse.

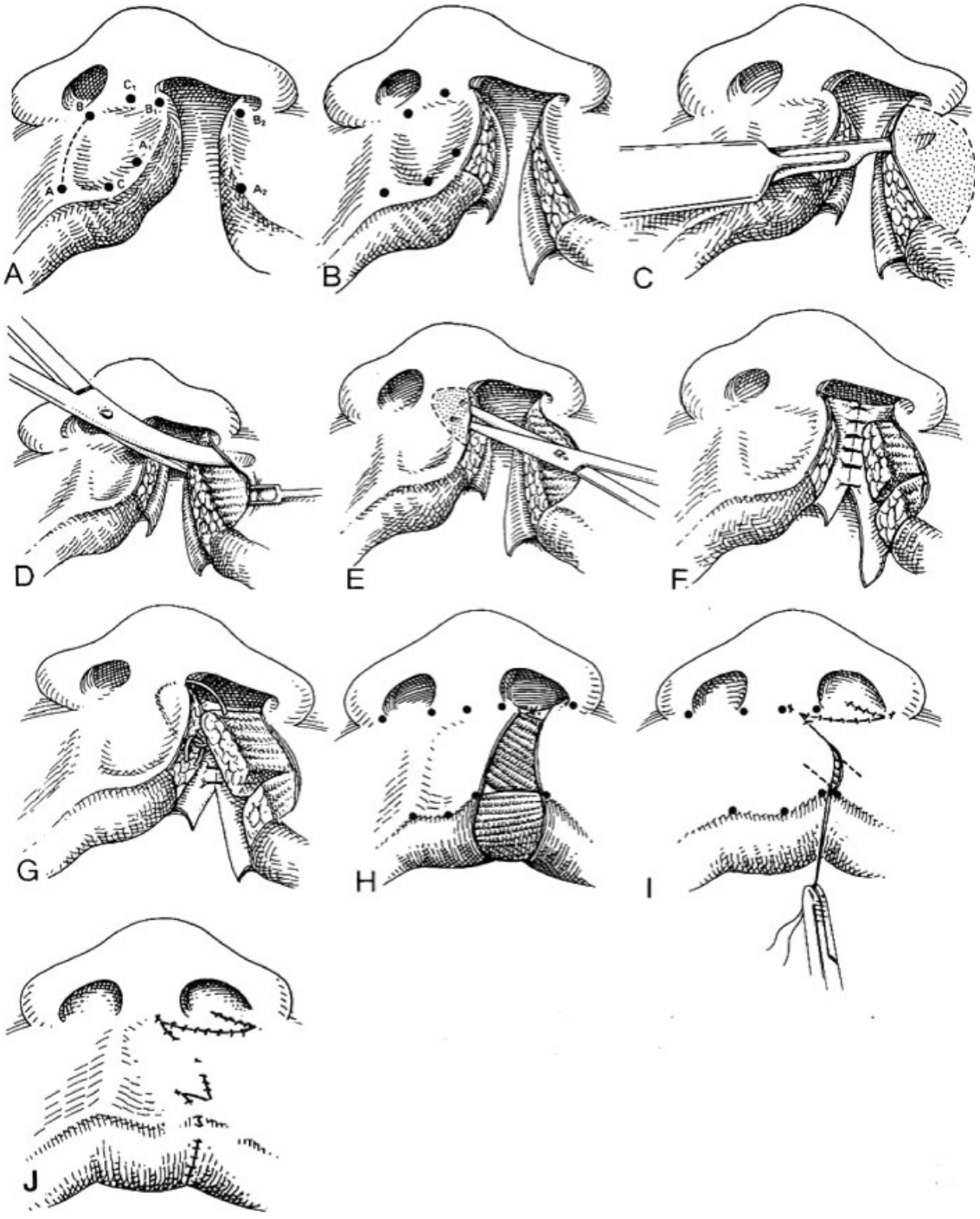

Figure 3 Muscle alignment repair. (A) Preoperative markings. (B) Mucosal flaps reflected. (C) Orbicularis muscle divided from dermal attachments. (D) Lateral muscle bundle divided from alar attachments. (E) Dissection of medial pocket to receive muscle flap. (F) Mucosal repair of buccal sulcus and nasal floor. Muscle flap divided. (G) Muscle flap drawn medially. (H) Muscle flap buried in medial pocket. (I) Upper Z-plasty executed, lower planned. (J) Closure complete. (From Kernahan DA. The functional cleft lip repair with muscle alignment. In: Kernahan DA, Rosenstein SW eds. Cleft Lip and Palate; a System of Management. Baltimore: Williams & Wilkins; 1990:149.)

Although this lip repair is part of the protocol the authors follow for patients with complete unilateral cleft lip and palate, any lip repair that incorporates a muscle repair and is done as a separate procedure in the appropriate sequence can result in success. Advantages of the functional cleft lip repair, however, are as follows. It is easy to learn, does not require a lip adhesion as an extra procedure, and is applicable to clefts of all widths. It follows basic principles of plastic surgery, so that a surgeon who performs an occasional lip closure can have

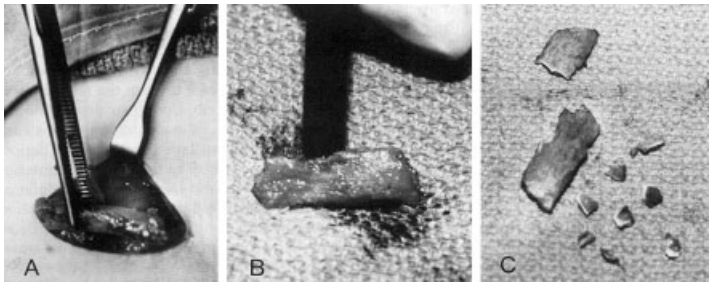

Figure 4 (A) After incision is made, dissection is done over sixth rib, and periosteum is dissected free from the rib, especially posteriorly, allowing traction to disarticulate rib at costocartilage junction. (B) Rib graft is split with an osteotome. (C) Anterior half of rib is kept intact; posterior half is cut into bone chips. (From Kernahan DA, Rosenstein SW, eds. Cleft Lip and Palate; a System of Management. Baltimore: Williams & Wilkins; 1990:182.)

success. This repair results in a natural vermilion and a lip that looks good at rest and in animation. The Z-plastys tend to disappear, making the scar imperceptible at conversational distance. Finally, because very little tissue is sacrificed and the alar crease and floor of the nose are normal at the end of the procedure, any revisions are usually minor touchups at the vermilion border, that is, a trim of lateral mucosal fullness, correction of a notched vermilion, or, at most, an additional Z-plasty above the vermilion to correct a short lip (occasionally seen in wide clefts).

EARLY ALVEOLAR BONE GRAFT PLACEMENT

Within weeks after the lip is repaired, there is generally a great amount of narrowing of the alveolar gap, and usually 2 to 3 months should pass to allow softening of the lip mucosa. When the two segments are almost touching (a 1- to 3-mm gap), the child is ready for placement of the onlay graft. The palatal appliance is in place during the procedure and for a minimum of 6 to 8 weeks after the operation (with the usual weekly removal for cleaning).

The rib graft is taken first, and a 2- to 3-cm incision is made generally over the fifth rib. This minimal scar falls into the inframammary crease and does not interfere with the breast bud. After spreading the soft tissues away, the muscle fascia is cut and the muscle split. The periosteum over the rib is cut in an H-style, with one limb over the costocartilage junction. The periosteum is freed up circumferentially on the segment of the rib to be harvested including the posterior side of the rib. The rib is easily disarticulated at the

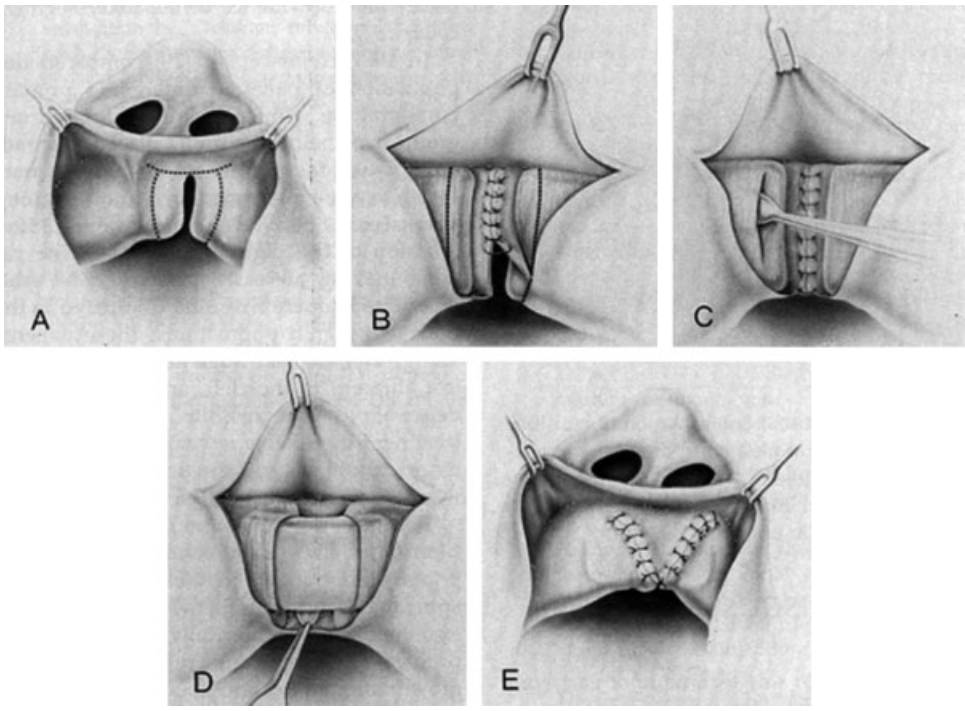

Figure 5 (A) Mucoperiosteal flaps are incised along cleft margins, and upper flag is incised along buccal sulcus. (B) Artist's representation of mucoperiosteal flaps as sutured to create posterior wall of pocket (usually three sutures are sufficient). (C) Remaining periosteum is stripped off margins of cleft alveolus and anterior maxilla. (D) Anterior strut of rib is placed in pocket with smaller bone chips packed behind and around it. (E) Buccal flap is brought down to achieve closure of anterior wall of pocket. Again, fewer structures are usually required than demonstrated in this artist's representation. In addition, a notch at the inferior cleft margin still remains. (From Kernahan DA, Rosenstein, SW eds. Cleft Lip and Palate; a System of Management. Baltimore: Williams & Wilkins; 1990:182.)

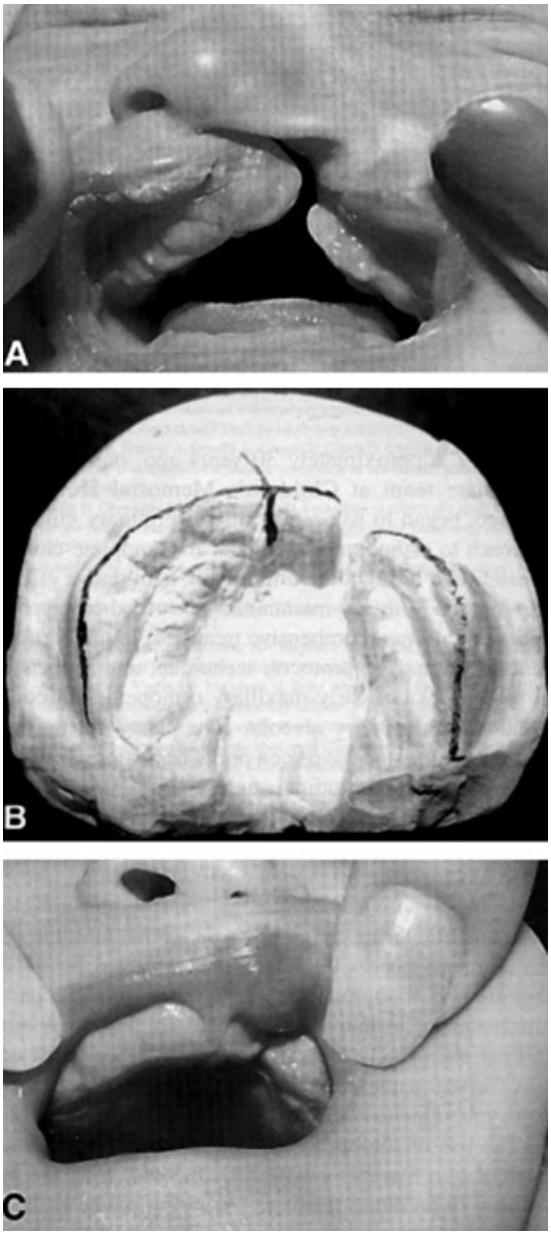

Figure 6 (A) Frontal facial view of patient at birth with left complete cleft of the lip, alveolus, and palate; (B) occlusal view of maxillary arch at birth; (C) intraoral view of maxillary segment alignment after lip closure demonstrating segment approximation with palatal plate in place and before segment stabilization via bone graft. (From Rosenstein SW. Two unilateral complete cleft lip and palate orthodontic cases treated from birth to adolescence. Am J Orthod Dentofacial Orthop 1999; 115:61.)

costocartilage junction, and a 1- to 1.5-cm segment of rib is removed with a bone cutter. By carefully staying within the periosteal pocket, there is no risk of pleural tear or bleeding from a costal vessel. The periosteum, muscle fascia, and skin are closed in separate layers (Fig. 4). The graft is then split, the anterior segment left intact or trimmed as necessary for fit, and the posterior segment cut into chips of bone. Because the periosteum is left intact and the cut periosteal flaps are sutured back, the rib regenerates within 6 to 8 weeks.

The cleft alveolus is then prepared for graft placement. Two flaps are incised, dissected free, and turned back on the medial and lateral alveolar cleft margins. They are sutured together to form the posterior lining. An incision is made in the buccal sulcus and a flap of mucosa elevated. The periosteum is stripped away from the maxilla above the medial and lateral segments of the alveolus for a distance of 4 to 5 mm on either side. Additional soft tissue dissection is done as necessary to aid closure of the flaps, and the alveolar flaps are then sutured to create a posterior lining. The strut of bone is placed in an onlay fashion over the maxilla just above the alveolar cleft, and the buccal flap is then brought downward and sutured to the cut edge of the mucosa at the inferior border of the medial and lateral alveolus and to the posterior flaps. The pocket is thus completely closed over the bone graft (Fig. 5).

BONE GRAFT INCORPORATION; TIMING OF PALATE CLOSURE

The appliance is used for an additional 6 to 8 weeks until graft incorporation results in a stable alveolar arch. Although it can be discontinued, most parents elect to continue the use of the appliance until the palate is closed as it facilitates feeding and is actually preferred by the infant. Generally, a minimum of 2 to 3 months passes before the palate is closed to allow softening of the mucosa and further narrowing of the cleft from the growth of the palatal shelves. Although the authors prefer a V-Y pushback with an intravelar veloplasty, the protocol can work with any type of complete cleft palate repair.

LONG-TERM ASSESSMENT OF EARLY ALVEOLAR BONE GRAFTING

This protocol has been followed without variation for over 39 years, and many patients remain available for long-term studies (Figs. 6–11). In addition to our own examination of our results, other researchers have evaluated our results and/or compared and reported on our data in conjunction with other protocols (Table 2). Long-term assessment of facial growth, status of lateral incisors adjacent to the cleft, incidence of orthognathic surgery, need for secondary grafting, and height of the alveolar ridge have been examined. We have over the years reported on an initial 53 cases, both unilateral and bilateral, and in 2003 a 35-year follow-up of an additional 82 cases was published.[6]

One of the first studies examining facial growth was a 13-year follow-up using cephalometric evaluation of 16 consecutive patients.[7] It showed that facial

Table 2 Collaborative Studies

Author	Type of Study	Size	Comments
Whitney et al (1984)[15]	Lateral cephalometric evaluation	526 films of primary grafted cleft cases through 13 yr of age	''no growth constraints''
Helms et al (1987)[21]	Panoral and dental radiographic; followed a minimum of 15 yr	20 primary grafts, 19 secondary grafts, 18 delayed grafts; all recorded minimum of 5 yr after graft	Primary grafts were superior to secondary and delayed grafts in all respects
Ross (1987)[10]	Lateral cephalometric radiographs (439)	Yearly films from 8 to 16 yr from 13 cleft palate centers worldwide	Primary graft sample showed A/P length of maxilla at 50th percentile and A/B difference a good 2.6'' (A ahead of B). Our center showed least degree of mandibular protrusion.
Trotman et al (1996)[17]	Lateral cephalometric evaluation	43 matched pairs: primary grafts to non-grafts; mean age, 10.32 yr	Grafted group faces were on average less maxillary protrusive, but mandible compensated by downward and backward rotation.
Rosenstein et al (1997)[14]	Computer-assisted tomographic scan and periapical/occlusal x-ray evaluation	14 primary grafts 11 yr after graft 43 and secondary grafts followed 3 yr	''. . . root support compared favorably; primary grafts, lateral incisor, 77%; canines, 83%; secondary grafts, lateral incisors, 80%; canines, 88%''
Long et al (1999)[18]	Lateral cephalometric evaluation	30 matched primary grafts and secondary grafts, 9 to 13 yr of age	''. . . little evidence . . . to indicate the presence of any significant maxillary deficiency resulting from the primary bone graft procedure.''
Hathaway et al (1999)[19]	Digitally recorded (reflex microscope) arch length and width of dental casts of 8 yr old patients having undergone primary grafts procedure following our technique and protocol	17 with primary grafts, 49 without grafts	''. . . no statistically significant difference for any arch dimension.''
Berkowitz and Duncan[22]	Three-dimensional study of total palatal surface area of unilateral maxillary cleft casts from birth through 16 yr of age	Casts from six different centers (only our center had primary grafting)	Total palate areas all grew in similar fashion

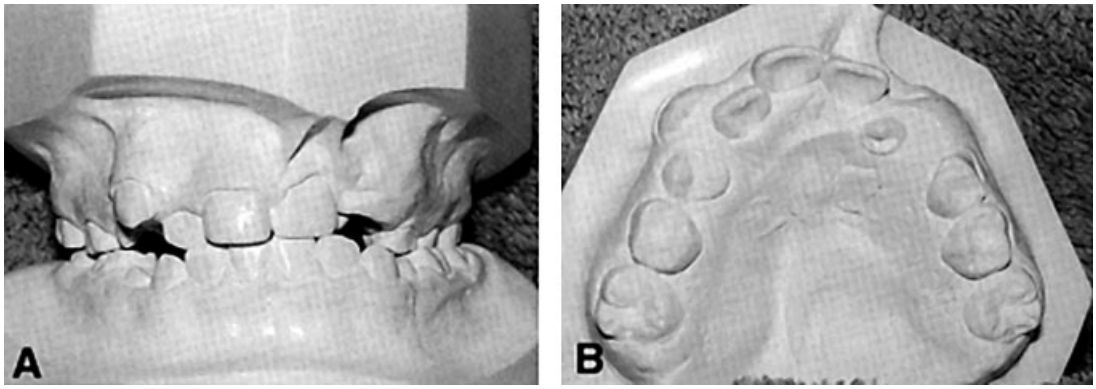

Figure 7 (A) Frontal view of study casts in occlusion after first phase of orthodontic treatment; (B) occlusal view of maxillary arch demonstrating ectopic fully developed right lateral incisor and undersized left (cleft side) lateral incisor. (From Rosenstein SW. Two unilateral complete cleft lip and palate orthodontic cases treated from birth to adolescence. Am J Orthod Dentofacial Orthop 1999;115:61.)

growth in the anterior posterior plane was not inhibited and maxillary segment alignment was actually better than in the similar nongrafted sample. In 1991[8] the next 37 consecutive patients were observed and it was found again that there were no adverse growth defects.

The need for orthognathic surgery (a soft indicator of facial growth problems) was reported as 22% in patients examined in 1991,[9] and in a later publication in which the mean age of the patients was 17.5 years, 18.29%.[6] This number is comparable to that in two studies examining the incidence of orthognathic surgery after secondary bone grafting, where 25% was reported.[10,11]

In 2003, Dado[12] reported on 115 patients available for follow-up and found that only 6 patients (5%) required regrafting. In addition, Dado et al examined the alveolar ridge at the site of the bone graft with three-dimensional computed tomography scans[13] and showed that the average bone ridge height at the lateral incisor was 8.7 mm with 76.5% root coverage and the average bone ridge height at the canine was 14.1 mm with 82.6% root coverage. This study had a mean follow-up of 11 years and these numbers compared favorably with

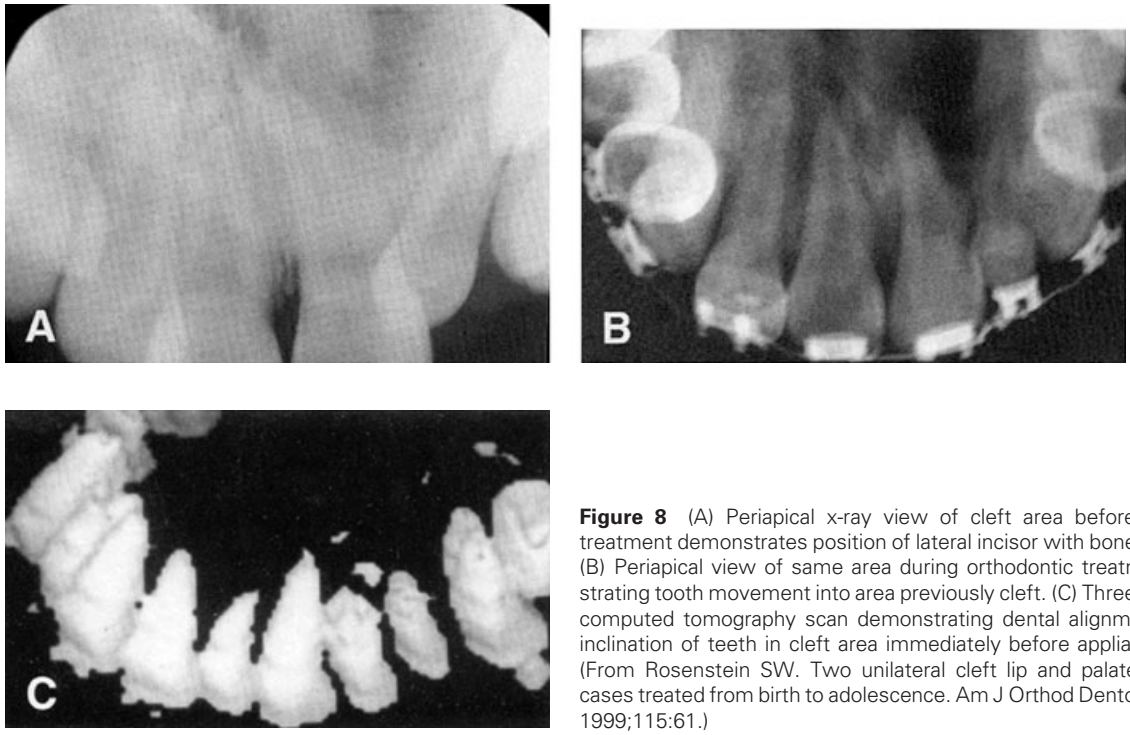

Figure 8 (A) Periapical x-ray view of cleft area before orthodontic treatment demonstrates position of lateral incisor with bone attachment. (B) Periapical view of same area during orthodontic treatment demonstrating tooth movement into area previously cleft. (C) Three-dimensional computed tomography scan demonstrating dental alignment and axial inclination of teeth in cleft area immediately before appliance removal. (From Rosenstein SW. Two unilateral cleft lip and palate orthodontic cases treated from birth to adolescence. Am J Orthod Dentofacial Orthop 1999;115:61.)

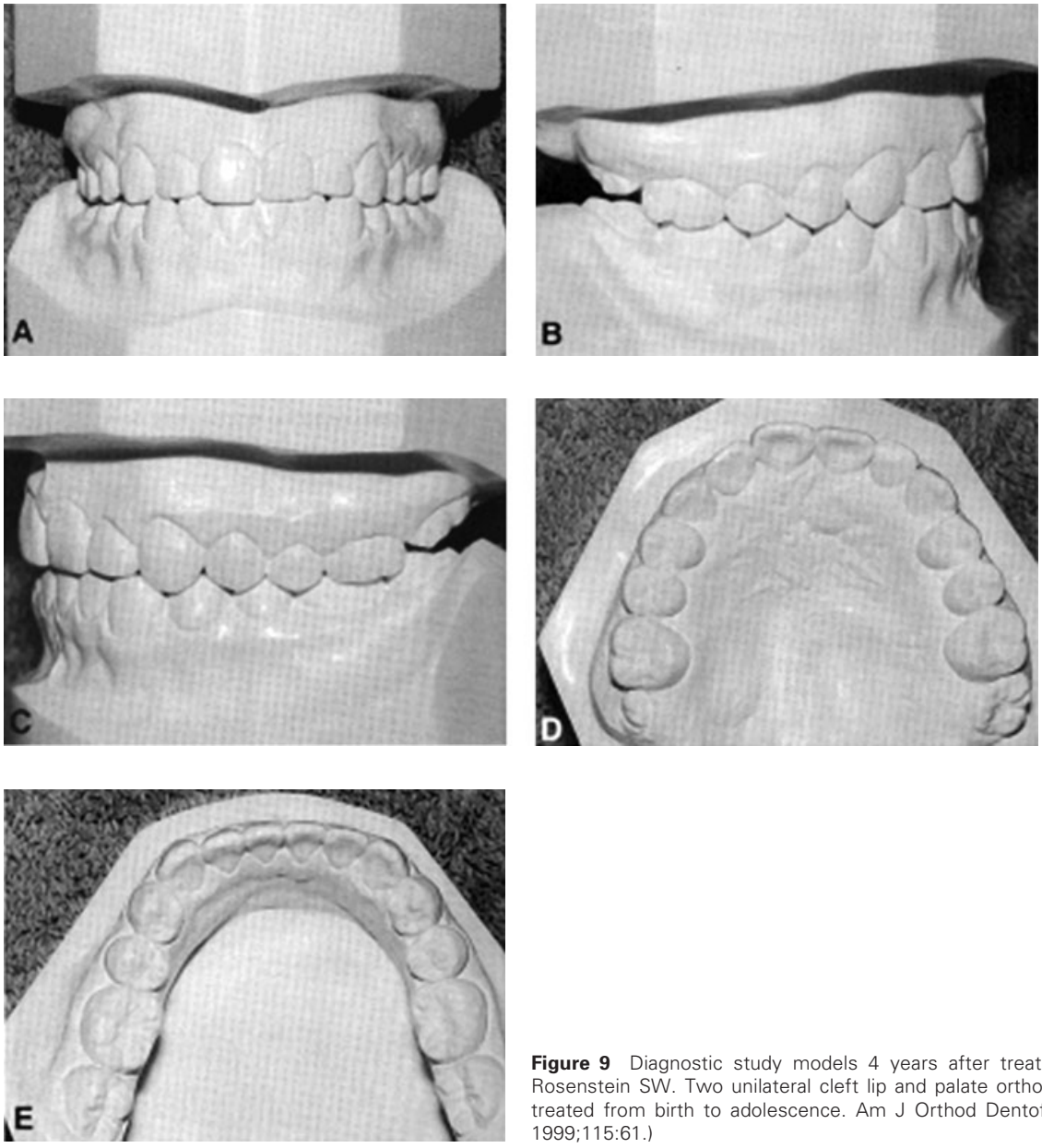

Figure 9 Diagnostic study models 4 years after treatment. (From Rosenstein SW. Two unilateral cleft lip and palate orthodontic cases treated from birth to adolescence. Am J Orthod Dentofacial Orthop 1999;115:61.)

those for patients who had received secondary grafts at the Lancaster Clinic, where the mean follow-up was 3 years; the ridge heights reported in this group were 80% and 87%, respectively.[14]

When cephalometric radiographs of the authors' patients were examined by others, no growth constraints were found,[15] and when compared with 13 other centers our group, with primary alveolar bone grafts, had the least amount of mandibular protrusion.[16] The maxillo-mandibular relationship of the primary grafted patients and facial growth have been shown to be similar to those of nongrafted patients[17] and secondary grafted patients.[18]

Finally, it should be noted that when the protocol is followed in a similar fashion, including sequence and steps, reproducible results are obtained and are being reported.[19]

DISCUSSION

The goals of any protocol for the treatment of cleft lip and palate include stabilization of the alveolar arch form with prevention of collapse of the lateral segments and provision of enough bone at the cleft site for lateral tooth eruption. By closely following a protocol that includes presurgical orthopedics, a lip repair with muscle realignment and closure, and onlay bone grafting as a separate and distinct procedure, these goals are reached. The muscular force of the repaired lip allows molding of the alveolar segments in a controlled environment

Figure 10 Periapical radiographic view of lateral incisor in area originally cleft, 4 years after appliance removal; note root length, tooth position, and alveolar bone integrity. (From Rosenstein SW. Two unilateral cleft lip and palate orthodontic cases treated from birth to adolescence. Am J Orthod Dentofacial Orthop 1999;115:61.)

without collapse of the lateral segments as long as the prosthesis is placed before lip closure. The bone graft maintains this favorable relationship of the segments and decreases the need for later palatal expansion. Secondary bone grafting is rarely needed. Bone at the site of the cleft alveolus improves the periodontal health of the teeth. The small pocket created and then closed at the site of the bone graft placement (when the two alveolar segments are almost touching) eliminates a nasal buccal fistula. The lip repair and bone graft placement are technically easy and relatively short procedures. The appliance, as constructed, does not require serial adjustments or replacements. The need for major secondary surgeries such as grafting and orthognathic surgery is markedly reduced, and any revision surgeries on the lip are generally minor in nature.

This protocol, when followed in a specific sequence of step-by-step procedures and interventions, results in a successful outcome for the child with cleft lip and palate. There is no need for the all too frequent team visits and numerous operative interventions. The appliance fabrication, cleft lip repair, and bone graft placement are uncomplicated and technically easy to learn. Most important, the results (i.e., maxillary growth, esthetic and functional results of the lip repair, and occlusion) are impressive in spite of a protocol that is straightforward and can be followed incorporating any type of lip repair with muscle realignment and any palate closure that results in an early complete closure.

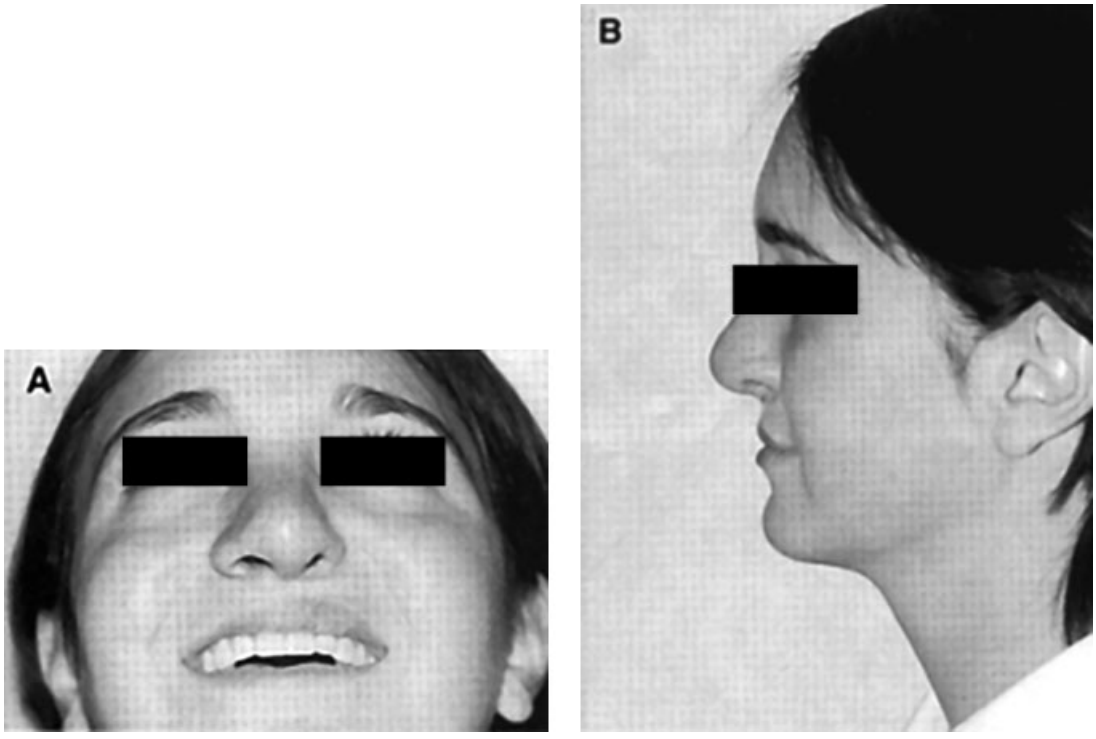

Figure 11 (A) Frontal facial view of patient smiling 4 years after orthodontic treatment; (B) cleft side profile view 4 years after orthodontic treatment. (From Rosenstein SW. Two unilateral cleft lip and palate orthodontic cases treated from birth to adolescence. Am J Orthod Dentofacial Orthop 1999;115:61.)

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